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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/414,384 10/07/99 CLARK

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021968 HM12/0801
INHALE THERAPEUTIC SYSTEMS INC
150 INDUSTRIAL ROAD
SAN CARLOS CA 94025

EXAMINER

BAWA, R

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

08/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/414,384

Applicant(s)

Clark

Examiner

Mr. Raj Bawa

Group Art Unit

1619



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1619

Detailed Action

(1) The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

(2) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Laube et al. (USP 5,320,094).

Laube et al. disclose a device for aerosol delivery of drug particles to a patient's lungs wherein the inspiratory rate is lowered by a flow rate limiting aperture. This is essentially the scope of claim 1 since the "limiting aperture" of Laube et al. reads on the claimed "flow resistance modulators".

All features of claim 1 are either identically disclosed by the cited art or clearly inherent to the disclosure thereof. Note that: (i) the cited art is analogous because it pertains to the field of the inventor's endeavor and is also reasonably pertinent to the particular problem with which the inventor is concerned. *In re Oetiker*, 977 F. 2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992); (ii) a comprising-type language does not exclude other steps, elements or materials. *Cues Inc. V.s. Polymer Industries*, U.S.P.Q. 2d 1847 (DC ND GA 1988); (iii) it is well established that the

Art Unit: 1619

claims are given the broadest interpretation during examination; and (iv) the burden is on the applicant to establish that the prior art product does not necessarily or inherently possess the function or property relied upon by applicant for novelty. *In re Best* 195 U.S.P.Q. 430.

(3) Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase “an initial target flow rate”; “high flow resistance”; and “initial time period” are vague and indefinite in the context recited because they are relative. AS a result, the metes and bounds of the patent protection desired would be unascertainable to one of ordinary skill in the art.

(ii) The phrase. “in a manner that is....” is vague. Cancellation requested.

It is the Examiner's position that the above phrases do not meet the threshold requirement of clarity and precision and are not in compliance for definiteness of 35 U.S.C. 112, second paragraph.

(iii) The claims are incomplete because some process/method step(s) are missing, such omission amounting to a gap between the steps. See MPEP 2173.05(I). A claim is indefinite when it merely recites some process/method steps without all active/positive steps defining how this process/method is actually practiced.

Art Unit: 1619


(4) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703)-308-2423. The examiner can normally be reached on Tuesday - Friday from 7:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703)-308-2328. The fax number for this group is (703)-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235.

Bawa/LR

July 19, 2000



**RAJ BAWA, Ph.D.
PRIMARY EXAMINER**